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21/9/02

Docket No. CRD-0957

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SM (52)
9/6/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : David Christian Lentz et al.

Serial No. : 09/966,447 Art Unit: 3763

Filed : September 28, 2001 Examiner:

For : COATED MEDICAL DEVICES

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on

January 7, 2002

(Date)

Carl J. Evens

Name of applicant, assignee, or Registered Representative


(Signature)

January 7, 2002

(Date of Signature)

Commissioner for Patents
Washington, D.C. 20231
Attention: Licensing and Review

RESPONSE TO FORTY-FIVE DAY LETTER

Dear Sir:

We David Christian Lentz, Gerard H. Llanos, Mark B. Roller, Angelo

George Scopelianos and Kevin Weadock

citizens of the United States of America

residing at 1371 Ginger Circle, Weston, FL 33326; 1514 Megan Circle,

Stewartsville, NJ 08886; 9 Quince Place, North Brunswick, NJ 08902;

7 John Stevens Road, Whitehouse Station, NJ 08889, and 105 Marten Road,

Princeton, NJ 08540, respectively

declare:

That we made and conceived the invention described and claimed in patent application:

Serial Number 09/966,447 filed in the United States of America on
September 28, 2001, titled Coated Medical Devices

Okay
Check and complete either I or II below

I. (For Inventors Employed by an Organization) That we made and conceived this invention while employed by Johnson & Johnson. That the invention is related to the work we are employed to perform and was made within the scope of our employment duties; That the invention was made during working hours and with the use of facilities, equipment materials, funds, information and services of Johnson & Johnson. Other relevant facts are: The invention relates to drug coated medical devices, including anastomosis devices. That to the best of our knowledge and belief (and/or) based upon information provided by _____

of _____

-OR-

II. (For self-employed Inventors)

That we made and conceived this invention on our own time using only our own facilities, equipment, materials, funds, information and services. Other relevant facts are _____

Check III and/or IV below as appropriate
That to the best of our knowledge and belief:

III. The invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy.

-AND/OR-



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CJE
DKT

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/916,447	09/28/01	Lentz, et al.	CRD-0957

Audley A. Ciampore **RECEIVED**
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

DEC 20 2001
PAT. DKT. SECTION

EXAMINER
ART UNIT PAPER NUMBER
3

DATE MAILED: 13 DEC 2001

Response due 1/27/02

LICENSING & REVIEW

**IF NO RESPONSE TO THIS NOTICE IS RECEIVED WITHIN FORTY-FIVE DAYS, A
FORMAL REQUIREMENT WILL BE ISSUED**

The subject matter of this application appears to:

be "useful in the production or utilization of special nuclear material or atomic energy" as recited in 42 U.S.C. 2182 (Department of Energy (DOE)).

"have significant utility in the conduct of aeronautical and space activities" as recited in 42 U.S.C. 2457 (National Aeronautics and Space Administration (NASA)).

Accordingly, no patent can issue on this application unless applicant(s) file a statement (under oath or in the form of a declaration as provided by 37 CFR 1.68) setting forth (1) the full facts concerning the circumstances under which the invention was made and conceived and (2) the relationship (if any) of the invention to the performance of any work under any contract or other arrangement with the Agency(ies) noted above. On the reverse side of this form is an example of an acceptable format for this statement. The language appearing in paragraphs III and/or IV of the example *must* appear if applicant is attempting to establish that no relationship (under item 2 above) exists.

If the invention disclosed in this application was developed under a contract, grant or cooperative agreement between the Agency indicated above and a person, small business or non-profit organization and rights to the invention have been determined by specific reference to 35 U.S.C. 202 in the contract, grant or cooperative agreement, then applicant need not submit the statement described above. Instead, applicant may file a verified statement (under oath or in the form of a declaration, 37 CFR 1.68) setting forth the information required by 35 U.S.C. 202(c)(6).

IF NO STATEMENT HAS BEEN RECEIVED WITHIN FORTY-FIVE DAYS OF THE MAIL DATE INDICATED ABOVE, a formal requirement for statement will then be issued. No provision is made for extension of the statutory thirty-day period for response to the formal requirement and the penalty for failure to file an acceptable and timely statement is abandonment of the application. Therefore, applicants are strongly encouraged to submit a statement at this time in order to avoid the issuance of a formal requirement.

IT IS IMPORTANT TO NOTE that the statement must accurately represent the property rights situation of the claimed invention if and when the application is found allowable. Thus, if during prosecution before the examiner, the claimed invention is so altered or the property rights situation so changed as to impact the accuracy of a statement submitted earlier, a supplemental statement must be filed. Failure to submit such additional information where appropriate may be considered a false representation of material facts and render the patent owner vulnerable to loss of patent rights and other sanctions as set forth in the statutes. The PTO will not review allowed applications for this possibility. The responsibility for complying with the statutes rests with the applicants.

Any questions regarding this requirement should be directed to Licensing and Review at (703) 306-4191.

**PLEASE DIRECT ALL COMMUNICATIONS RELATING TO THIS MATTER TO THE
ATTENTION OF LICENSING AND REVIEW**

The following is an example of an acceptable property rights statement. Statements of this type are, of course, only suitable for situations in which NO Agency funds or other considerations were involved in the making or conception of the invention. While this example is in the form of a declaration, a sworn document is equally acceptable.

I (We) _____
citizens of _____
residing at _____
declare:

That I (we) made and conceived the invention described and claimed in patent application:

Serial Number _____ filed in the United States of America on _____
titled _____

(Check and complete either I or II below)

I. (For Inventors Employed by an Organization) That I (we) made and conceived this invention while employed by _____ . That the invention is related to the work I am (we are) employed to perform and was made within the scope of my (our) employment duties; That the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of _____ . Other relevant facts are _____
(name of employer)

That to the best of my (our) knowledge and belief (and/or) based upon information provided by _____
of _____ :
—OR—

II. (For Self-Employed Inventors) That I (we) made and conceived this invention on my (our) own time using only my (our) own facilities, equipment, materials, funds, information and services. Other relevant facts are _____

(Check III and/or IV below as appropriate)

That to the best of my (our) knowledge and belief:

III. The invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy.

—AND/OR—

IV. The invention was not made (conceived or first actually reduced to practice) under nor is there any relationship of the invention to the performance of any work under any contract of the National Aeronautics and Space Administration.

The undersigned inventor(s) declare further that all statements made herein of his or her (their) own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Inventor's Signature: _____

Post Office Address: _____

Date: _____

Inventor's Signature: _____

Post Office Address: _____

Date: _____